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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,429	11/19/2003	Jeffrey B. Etter	42830-10009	7009

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,429

Applicant(s)

ETTER, JEFFREY B.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-40 and 94-105 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26-40 and 94-105 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-30-04, 5-25-05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims included in the prosecution are 26-40 and 94-105.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 26-40 and 94-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debenedetti et al (6,063,910) in view of Manning et al (5,770,559) or vice versa (both are of record).

Debenedetti et al disclose a method of preparation of protein microparticles using a solvent and anti-solvent system. The antisolvents are supercritical fluids including carbon dioxide. The organic solvents are selected from at least one of ethanol, DMSO, dimethylamine and others. The method involves preparing a solution of the protein in an organic solvent through a continuum of supercritical antisolvent fluid and precipitating the protein (abstract, col. 2, line 23 through col. 3, line 16, col. 6, lines 18-32 and examples). Although Debenedetti et al teach that controlled release formulations can be prepared using biocompatible polymers (col. 4, lines 24-40 and col. 6, lines 43-51), they do not explicitly teach that the feed solution contain the polymer also.

Manning et al disclose a method of preparation of pharmaceutical powders containing either proteinaceous or non-proteinaceous active agents. The method

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involves dissolving the active agent and a polymer in an organic solvent and subjecting the mixture to gas antisolvent precipitation using a supercritical gas antisolvent such as carbon dioxide. The organic solvents include alcohols and chlorocarbons and others.

The amount of the drug is 0.5 to 5.0 % relative to the amount of the polymer (abstract, col. 4, line 45 through col. 6, line 49, col. 7, lines 3-18, col. 12, lines 13-42, col. 14, lines 40-57, examples and claims). What is lacking in Manning et al is the use of a mixture of organic solvents.

It would have been obvious to include a biodegradable polymer in the feed solution of Debenedetti et al with a reasonable expectation of success, since such an inclusion would result in a controlled release formulation and the reference of Manning et al teaches that in similar method, one can include the polymer in the feed solution which is added with an antisolvent. Alternately, to include a mixture of organic solvents in the feed solution would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since Debenedetti et al teach that a mixture of organic solvents could be used before adding the feed solution to the antisolvent.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 26-40 and 94-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,669,960. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the patent and instant application are drawn to the same method of preparation of drug-containing particulate product. Instant claims are generic with respect to the ratios of solvents whereas the patented claims recite ratios of 10:90 to 99:1. It would have been obvious to vary the amounts of the solvents in the method of said patent with a reasonable expectation of success. Instant claims also encompass the ratios of the solvents recited in the claims of said patent and thus anticipate the ratios.

3. Claims 26-40 and 94-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. Patent No. 6,761,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the patent and instant application are drawn to the same method of preparation of drug-containing particulate

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product. Instant claims are generic with respect to the ratios of solvents whereas the patented claims recite ratios of 10:90 to 99:1. Instant claims are also generic with respect to the drug. The patented claims recite insulin as the drug. It would have been obvious to vary the amounts of the solvents or use drugs other than insulin in the method of said patent with a reasonable expectation of success. Instant claims also encompass the ratios of the solvents and insulin recited in the claims of said patent and thus anticipate the ratios and the drug.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK